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Assistant Commissioner for Patents

Washington, D.C. 20231 on August 1, 2002

Doran R. Pace, Patent Attorney

ELECTION UNDER 35 USC §121
Examining Group 1636
Patent Application
Docket No. GJE-39
Serial No. 09/486,676

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Celine X. Qian
Art Unit : 1636
Applicant : Andrea Crisanti
Serial No. : 09/486,676
Filed : March 1, 2000
Conf. No. : 9050
For : Conjugates that Contain the Homeodomain of Antennapedia

Assistant Commissioner for Patents
Washington, D.C. 20231

ELECTION UNDER 35 USC §121

Sir:

In response to the written Restriction Requirement dated June 1, 2002 in the above-identified patent application, Applicant hereby elects to prosecute the invention of Group I (claims 1-9, 19, 20, 22, and 23), with traverse. Applicant notes that the "Disposition of Claims" section on the Office Action Summary page of the written Restriction Requirement correctly indicates that claims 1-14, 16, 17, and 19-24 are pending in the subject application in view of the Preliminary Amendment filed on March 1, 2000; however, claim 15 (in Group I) and claim 18 (in Group IV) were included in the Examiner's written Restriction Requirement. Therefore, Applicant wishes to clarify that claims 15 and 18 are no longer pending in the subject application.

In the instant Restriction Requirement, the Examiner asserts that the inventions listed as Groups I to V do not relate to a single general inventive concept because they lack the same or corresponding special technical features. Specifically, the Examiner asserts that the "special

technical feature” of Group I is a fusion protein comprising antennapedia homeodomain. The Examiner further asserts that the fusion protein lacks novelty (citing the Schutze-Redelmeier *et al.* (1996) reference) and, therefore, does not make a contribution over the prior art.

Applicant respectfully asserts that there is unity of invention for the claimed subject matter. As the Examiner is aware, under PCT Rule 13.1, there is unity of invention if all of the inventions in an application are so linked as to form a single general inventive concept. PCT Rule 13.2 states that unity of invention exists where there is a technical relationship among the claimed inventions involving one or more of the same or corresponding “special technical features.” The expression “special technical features” is defined in the rules as those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Applicant respectfully asserts that the special technical features that link the claims in the subject application define a contribution which each of the claims makes over the prior art. Applicant further asserts that none of the references, including the Schutze-Redelmeier *et al.* reference, cited in the International Search Report of the PCT application corresponding to the subject U.S. national application disclose a conjugate of antennapedia having a non-denatured region. Moreover, in regard to claim 4, Applicant submits that none of the references disclose conjugates of antennapedia that have a second region with greater than 100 amino acids. The Schutze-Redelmeier *et al.* reference cited by the Examiner discloses the use of the homeodomain of antennapedia to translocate antigens across the cell membrane. The conjugates were purified according to Perez *et al.*, *J. Cell Sci.* (1992) 102:717-722, which shows that a high salt (KC1) concentration was used in purification. Thus, the Schutze-Redelmeier *et al.* reference does not teach a conjugate under non-denaturing conditions. The conjugates are shown in Figure 1 on page 651 and it is clear that no conjugate disclosed therein comprises a second region of greater than 100 amino acids. Applicant respectfully asserts that the special technical feature of the claimed invention is novel and non-obvious over the prior art, including the Schutze-Redelmeier *et al.* reference.

Applicant would also like to bring to the Examiner’s attention that during the international phase, the PCT application corresponding to the subject U.S. national application was determined to have unity of invention among all claims. Moreover, the International Preliminary Examination Report (IPER) in the corresponding PCT application indicated that “the subject matter of the claims

is novel and inventive” (emphasis added) and provided a commentary on the reasons why this decision was reached. Specifically, the IPER states that:

“the present invention shows that large proteins greater than 100 amino acids can be translocated across a cell membrane using the Antennapedia homeodomain. An important requirement therefore is the use of a conjugate wherein the Antennapedia part has not been denaturated [sic]. This teaching cannot be derived from the cited prior art in an obvious way. In fact, the prior art even applies conjugates which are clearly denaturated [sic] and provides experiments investigating this phenomenon [sic] (see e.g. D2, the end of Introduction).”

The claims restricted to Group III merely recite a composition comprising the conjugate of claim 1 (Group I) combined with a pharmaceutically-acceptable carrier. Moreover, Annex B of the Administrative Instruction Under the PCT (see, for example, Part 2, Example 17 therein) specifically indicates that a claim to Protein X and a claim to a DNA sequence encoding Protein X do, in fact, have unity of Invention. The claims in Group I and Group II of the subject application are directed to a protein and a nucleic acid encoding that protein, respectively. Therefore, Applicant respectfully asserts that, at a minimum, there is unity of invention between the invention of Group I, Group II, and Group III.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the Restriction Requirement. An indication that there is unity of invention for all the claims is respectfully requested.

Applicant invites the Examiner to call the undersigned if clarification is needed or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,



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